



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | |
|---|--|---|---------------------|
| Applicant's or agent's file reference 80442 WO | FOR FURTHER ACTION | | See Form PCT/PEA416 |
| International application No. PCT/EP2005/00808 | International filing date (day/month/year) 27.01.2005 | Priority date (day/month/year) 28.01.2004 | |
| International Patent Classification (IPC) or national classification and IPC INV. A23L1/30 A61K31/205 | | | |
| Applicant NESTEC S.A. et al. | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 3 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 23.08.2005 | | Date of completion of this report 19.06.2006 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Uhl, M Telephone No. +49 89 2399-8654  | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/000808

Box No. I Basis of the report

1. With regard to the language, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements* of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-17 as originally filed

Claims, Numbers

1-18 received on 20.03.2006 with letter of 17.03.2006

Drawings, Sheets

1/1 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**International application No.
PCT/EP2005/000808**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-3, 5-17

because:

☒ the said international application, or the said claims Nos. 1-3, 5-17 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for the said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**International application No.
PCT/EP2005/000808

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 4,5, 18

No: Claims

Inventive step (IS) Yes: Claims 4,5

No: Claims 18

Industrial applicability (IA) Yes: Claims 4,5,18

No: Claims

2. Citations and explanations (Rule 70.7):**see separate sheet**

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2005/000808

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Do: RU-C1-2 187 229

D2: US 2003/060503

D3: WO 02/11717

D4: US 2002/077349

D5: US-B1-6 503 506

1. Claims 1-3 and 6-17 are still -even after reformulation- formulated in a way that it includes non-medical as well as medical uses as ingestible composition includes non-medicaments as well (see claim 16). However, non-medical uses have to be claimed differently. To establish novelty, different features as the intended therapeutic indication have to be defined in view of the prior art. For the time being the non-therapeutic part of these claims is not novel over the prior art as for a non-therapeutic use the aim to increase the lipid secretion in the sebum is not relevant. Only in the strictly followed second-medical-use format directed to the use to manufacture a medicament -and not only a composition- for the treatment of a disease -and not only an unspecified increase of the lipid secretion in the sebum- the indication can establish novelty, like in the subject matter of claims 4 and 5. In view of the documents as cited in the international search report the subject matter of claims 1-3 and 6-17 are not novel over the prior art in view of this non-therapeutic part of subject matter included in the contested claims. DO discloses compositions with L-carnitine and -among others- vitamin C which is a known antioxidative agent. It is not necessary that this is discussed in Do. D2 and D3 disclose compositions with L-carnitine and coenzyme Q and alpha- lipoic acid. D4 discloses lipoic acid as antioxidant and a carnitine product, which also comprises L-carnitine. D5 discloses compositions comprising L-carnitine and antioxidants (fruit polyphenols). None of them discloses the aim to increase the lipid secretion in sebum. However this is not relevant for the evaluation of the non-therapeutic part of the contested claims as set out above.
2. The subject matter of claims 4 and 5 with a clear reference to dermatitis as medical indication is sufficiently clear second-medical-use and considered novel and inventive

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/EP2005/000808

in view of the prior art cited in the international search report (Art.33(1),(2) and (3) PCT).

3. The subject matter of claim 18 is new by the choice of special antioxidative agents. However all those antioxidative agents are well known equivalents of those already used together with L-carnitine in food or food supplements or pet food. Again their acting together in the human or animal skin is not relevant for evaluation. For the inventive step of the subject matter of a product claim the only question is whether it was evident to combine L-carnitine and antioxidants in e.g. food or food supplements. In case the special choice of antioxidants has an technical effect this should be shown by comparative experimentation with the closest prior art (Article 33(1) and (3)PCT).

PCT/EP2005/000808
NESTEC S.A.
Our ref.: 80442 WO

Claims

- 5 1 Use of L-carnitine and at least a component having an anti-oxidative activity for making an ingestable composition for the stimulation of the lipid metabolism in the skin of an animal or a human being for treating dermatitis.
2. The use according to claim 1, for increasing the lipid secretion in the sebum and/or for
10 producing a protective sebum layer on the skin.
3. The use according to claim 1, for treating ulcerative dermatitis.
4. Use of L-carnitine and at least a component having an anti-oxidative activity for the
15 preparation of a medicament for the stimulation of the lipid metabolism in the skin of an animal or a human for preventing the onset or incidence of ulcers associated with diabetes, of circulation disturbances, of physical, chemical or microbial noxae or of eczema, said medicament being an ingestable composition.
- 20 5. Use of L-carnitine and at least a component having an anti-oxidative activity for the preparation of a medicament for the stimulation of the lipid metabolism in the skin of an animal or a human being for a reduction of itching and improving a dry skin condition or sensible skin condition, said medicament being an ingestable composition.
- 25 6. Use of L-carnitine and at least a component having an anti-oxidative activity for making an ingestable composition for the stimulation of the lipid metabolism in the skin of an animal or a human being, said stimulation of the lipid metabolism comprising an increasing of the lipid secretion in the sebum.
- 30 7. The use according to claim 4, 5 and 6, for producing a protective sebum layer on the skin.

8. The use according to one of claim 4, 5, 6 and 7, for reducing dry skin or itching.
9. The use according to any of the preceding claims, wherein the component exhibiting an anti-oxidative activity is selected from the group consisting of vitamin E; vitamin C; carotenoids; ubiquinones; tea catechins; coffee extracts containing polyphenols and/or diterpenes; ginkgo biloba extracts; grape or grape seed extracts rich in proanthocyanidins; spice extracts; soy extracts containing isoflavones, phytoestrogens; ursodeoxycholic acid; ursolic acid; ginseng and ginsenosides and natural sources thereof; a source of thiols, preferably lipoic acid, cysteine, cystine, methionine, S-adenosyl-methionine, taurine, glutathione or natural sources thereof; or mixtures thereof.
10. The use according to any of the preceding claims, wherein the amount of L-carnitine administered daily is from at 1mg to 1 g per kg of body weight / day, preferably of from 5 mg to 250 mg per kg of body weight / day.
11. The use according to any of the preceding claims wherein the amount of the component having an anti-oxidative activity is from 0.025 mg to 250mg per kg of body weight / day.
12. The use according to any of the preceding claims, wherein the ingestable composition contains a source of fat, which comprises unsaturated fatty acids or is enriched with unsaturated fatty acids.
13. The use according to claim 12, wherein the unsaturated fatty acids is alpha-linolenic acid.
14. The use according to any of the claims 12 or 13, wherein said source of fat is selected from the group consisting of an animal fat, preferably tallow or fish oil, more preferably beef tallow, or an vegetable fat, preferably corn oil, sunflower oil, safflower oil, rape seed oil, soy bean oil, olive oil, borage oil, blackcurrent seed oil.
15. The use according to any of the claims 12 to 14, wherein the amount of said source of fat in the composition is at least 0.1 % by weight on basis of the total weight of the

composition.

164. The use according to any of the preceding claims, wherein the ingestable composition is a medicament, a food or a functional food, a nutritionally complete pet or human food or a dietary supplement.

17. Use of L-carnitine and at least a component having an anti-oxidative activity and being selected from the group consisting of ubiquinones; tea catechins; coffee extracts containing polyphenols and/or diterpenes; ginkgo biloba extracts; grape or grape seed extracts rich in proanthocyanidins; spice extracts; soy extracts containing isoflavones, phytoestrogens; ursodeoxycholic acid; ursolic acid; ginseng and ginsenosides and natural sources thereof; cysteine, cystine, methionine, S-adenosyl-methionine, taurine or natural sources thereof; or mixtures thereof; or being selected from the group of mixtures of vitamin E or derivatives thereof with two or three of vitamin C or derivatives thereof; grape seed extract; and cysteine, for making an ingestable composition,

said ingestable composition being intended for the stimulation of the lipid metabolism in the skin of an animal or a human being, said ingestable composition being a food or a functional food, a nutritionally complete pet or human food or a dietary supplement.

185. An ingestable composition selected from a medicament, a food, a functional food, a nutritional complete pet or human food, and a dietary comprising L-carnitine and at least a component having an anti-oxidative activity and being selected from the group consisting of ubiquinones; tea catechins; coffee extracts containing polyphenols and/or diterpenes; ginkgo biloba extracts; grape or grape seed extracts rich in proanthocyanidins; spice extracts; soy extracts containing isoflavones, phytoestrogens; ursodeoxycholic acid; ursolic acid; ginseng and ginsenosides and natural sources thereof; cysteine, cystine, methionine, S-adenosyl-methionine, taurine or natural sources thereof; or mixtures thereof; or being selected from the group of mixtures of vitamin E or derivatives thereof with two or three of vitamin C or derivatives thereof; grape seed extract; and cysteine.